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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,215	12/19/2000	Qi Jia	UNI.15/D	7672

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/21/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

'Office Action Summary

Application No.

09/741,215

Applicant(s)

Jia et al.

Examiner

Patricia Patten

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3+4 20) ☐ Other:

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DETAILED ACTION

Claims 13-21 are pending in the application and were presented for examination on the merits.

Abstract

The Abstract contains wording which appears to come from a web site address. The Examiner has redlined through this writing as it does not appear to correspond with the content of the abstract (Rule 126).

Claim Objections

Claim objected to because of the following informalities:

Claim 13, preamble recites 'a isoquinoline alkaloid' which should appropriately read 'an isoquinoline alkaloid.' Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim s 13 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, part (a) recites 'the ground biomass.' This term lacks antecedent basis in the claim.

Claim 13 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The preamble of Claim 13 recites a method for the isolation and purification of a[n] isoquinoline alkaloid, however, does not contain any steps for further purification (which is found in claim 14). It is suggested that the limitation of claim 14 be incorporated into claim 13 in order to overcome this rejection.

Claims 17-20 recite the terms 'dynamic mode' and 'static mode.' These terms are not clearly defined in the Instant disclosure, and are not readily found in the prior art and are therefore deemed indefinite. Applicant is asked to amend the claims accordingly, or alternatively, provide a prior art reference which would clearly indicate that these terms are well known in the art of purification in order to overcome this rejection. For the purposes of prior art, these terms were searched as though they were 'vat extractor' and 'column extractor' respectively.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehlretter et al. (US 2,715,627). Claims 13-15 are drawn to a method for isolation and purification of an isoquinoline alkaloid via extraction of a ground biomass of a plant with a solvent, neutralization and further concentration. Claims are further drawn to wherein the extract is purified by a chromatographic method, and wherein the plant is selected from a group of specific plant families and genus.

Extraction of isoquinoline alkaloids from plants such as poppy (*Papaver somniferum*-family *Papaveraceae*) was well known in the art. The most prevalent and widely extracted isoquinoline alkaloid prepared from poppy was morphine, a well known pain reliever/sedative. Mehlretter et al. (US 2,175,627) for example, taught a protocol for the extraction of morphine from poppy which included extraction with mineral acid, alkali precipitation (neutralization), evaporation (concentration), and then optionally, purification via ion exchange chromatography (col.2, lines 44-65).

Mehlretter et al. specifically taught that the dried poppy straw was 'tempered and flaked.' The Examiner has given the term 'flaked' it's broadest, most reasonable interpretation and

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deemed that this term meant ground, or cut very fine. Thus, it is deemed that the term 'flaked' encompassed the term 'ground' which is recited in the Instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims ¹³~~14~~-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehlretter et al. (US 2,715,627). Claims 17-20 are drawn to wherein the biomass is extracted in a dynamic mode such as a vat extractor, or in a static mode, such as a column extractor.

The teachings of Mehlretter et al. were discussed supra. Mehlretter et al. did not specifically discuss where the extract was carried out via dynamic mode or static mode.

Taken from the Instant disclosure, a 'vat extractor' appears to be similar to a large blender. One of ordinary skill in the art would have been motivated to have suitably blended the crude plant material/solvent in order to have allowed all of the solvent to penetrate every possible exposed surface area of plant material, which would thereby offer a larger yield of product.

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The column extractor, as described in the Instant disclosure (i.e.; p. 17) appears to be a container which holds the crude plant material, whereby said container is provided with an inlet and outlet in order to allow the solvent to pass over the crude plant material and subsequently be collected at the outlet. This apparatus would have proven equivalent to mixing the crude plant material with solvent, and then filtering or evaporating the solvent therefrom. It is deemed that the inclusion of the apparatus does not render the invention novel; MPEP 2144.04 III.

Automating a manual activity, states: 'The court held that broadly providing a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.' In the instant case, although the prior art reference did not use either a vat extraction method, or a column extractor, the manual mixing of the crude plant material with the solvent followed by evaporation and/or removal of the solvent would have accomplished the same results as would a vat extractor and/or column extractor and thus, would have been obvious to one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

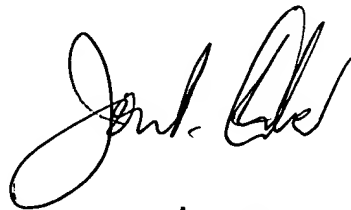
No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jon P. Weber". The signature is stylized with a large, looping initial "J" and a cursive "P. Weber".

**Jon P. Weber, Ph.D.
Primary Examiner**